Management Review meeting of SNSC performance based on internal audit
Audit cycle-II - July to December 2012
Dated 18.03.2013

Attendance: By list (list enclosed). The representations were from the SN main lab for Hematology and Clinical Pathology, Routine Biochemistry, Sp. Biochemistry, Microbiology and Serology, Histopathology, Cytogenetics and the Support Services, CSFU, HRD, Commercial, Housekeeping, Biomedical, Electrical, IT and all Internal auditors.

The stipulated agenda points presented by the Quality Manager, Dr. N. Angayarkanni.

1. Follow up of previous management review
2. Status of Corrective and Preventive Actions taken (CAPA)
3. Report from Managerial and supervisory personnel of each of the lab on QC/Measures
4. Out come of recent internal audits, NC’s.
5. Assessments of external bodies.
6. Outcome of Quality Control: External/Internal/Daily of each lab: EQAS, ILQC.
7. Volume and type of work undertaken.
8. Feedback including complaints and other relevant factors for Internal and external
9. Quality Indicators for monitoring the laboratories contribution to patient care
11. Monitoring Turn around time.
12. Continual improvements.
14. Points for Discussion for action

1. Details Key points of the previous Management Review Meeting Minutes was reviewed

Audit Team Members and Audited labs/support services:

- Quality System: Ms.G.Kamatchi
- Front Office & Pre analytical area: Dr.R.Gayathri & Ms.Y.Faritha Banu
- Clinical Pathology and Hematology: Ms.R.Punitham
- Clinical and Special Biochemistry: Dr.R.Gayathri
- Clinical Microbiology and Serology: Ms.K.Vanitha
- Histopathology and Cytogenetics: Ms.B.Mohanambal
- Human Resource Department: Dr.Doreen Gracias & Ms.B.Mohanambal
- Commercial: Ms.Saumya.T.S
- Central Sterilization Facility Unit: Dr.K.Coral
- Biomedical Department: Ms.Saumya.T.S
- IT Dept: Dr.N.Angayarkanni

Issue Date: 25.3.13
Prepared & Issued by: Quality Manager

Approved by: Management Representative
Non NABL:
• SNSC Collection Centre – R. Selvi.
• NSN Lab: Not done
• Cytogenetics: Ms. U. Jayanthi

2. Status of Corrective and Preventive Actions taken (CAPA) The QC reports of all the laboratories are verified every quarter. The following are the details of CAPA filed:
   a. EQAS Clinical Hematology & Clinical Pathology lab: Unsatisfactory – 3 CAPA filed
   b. EQAS Clinical Biochemistry: Unsatisfactory – 3 CAPA filed
   c. EQAS Microbiology & Serology: Unsatisfactory – 1 CAPA filed
   d. ILQC Histopathology: Unsatisfactory – 1 CAPA filed

3. Report from Managerial and supervisory personnel of each of the lab on QC/Measures.
   a. Copy report issued by the respective consultant secretary.
   b. NABH requirement: The copy reports are given by the floor coordinator
   c. On line verification done by the technician and supervisors in all laboratories implemented completely.
   e. Lab reports can viewed at all locations by the consultant and nursing dept, physician by HMS and EMR.
   f. Training classes conducted in each lab has been entered in HMS and Heads of the lab shall ensure the same.
   g. Feedback analysis for the patient is done by HMS by the Clinical Haematology & Clinical Pathology lab. IT shall give details on request by the Lab
   h. Details of the QC in each lab discussed as given by the Dy Tech managers

4. The Second internal audit July to December’12 has been conducted by the trained and approved internal auditors and details are given the Technical manager / internal auditors and Dy Tech managers of each lab as supervised.

5. Assessments of external bodies: updated in all the laboratories:
   a. Tamil Nadu Pollution control Board certificate for disposal of waste Renewal of Certificate has done on October 2012. Waste disposal is done by G.J multiclave it will continue. For renewal of the agreement done on May 2012.
   b. Assessment of the referral labs updated by all the departments.
6. Outcome of Quality Control: External/Internal/Daily of each lab: EQAS, ILQC.
   • The QC reports of all the laboratories (Refer Point No.2 and 3)

7. New tests added /removed from the scope
   • Revised Scope : We have received the NABL certificate with revised scope on 18.05.2012 with validity period of 4.8.2011 to 3.8.2013.

   a. Clinical Hematology : 19 and clinical pathology : 20
   b. Clinical and special Biochemistry : 26
   c. Clinical Microbiology and Serology : 26
   d. Clinical Histopathology : 14
   e. Cytopathology : 8

   Total: 113 Tests

   • Number of tests accredited as in the Scope :

   a. CI Microbiology and Serology : Removed Immuno fluorescence stain for HSV
   b. Clinical and Special Biochemistry : Amino acid profile CV% changed as in revised scope Dated : 18.05.2012

   • New signing Authority

   a. Request for Dr. K. Coral is pending and will be addressed during next recertification audit in Aug 13.

   b. Dr.Gayathri’s name has been sent for authorized signature for the department of Microbiology and Serology. It shall be resubmitted for on site verification during next external audit.

   • New post created : Nil. However the technical staff number is adequate.

   • Promotions/resignations :

   a. Two Senior tech completed the probation (Mr. Samvel & Ms.Rubella Nancy)
   b. One Junior Executive got the direct confirmation based on year of experience. (Ms. Praveena)
   c. Mr.Sasikumar Senior Lab Technician transferred to CSFU
8. Feedback analysis:

a. **Internal customer feedback:** The observed measures were above the expected in all the laboratories. Three of the Consultants had raised querreis/suggestions. All the three suggestions were addressed, action taken and settled.

b. **External Customers:** Feedbacks (after grouping them on similarity in issues) were analyzed (Jul – Dec 2012) proceeded with action and settled.

9. **Quality Indicators for monitoring the laboratories contribution to patient care as measured**
   a. **Specimens receiving on time** - Satisfactory and met the objectives in all the labs.
   b. **Turn around time** – Microbiology /Histopathology – Below the objective at 2 instances - 2 CAPA filed
   c. **Machine downtime** – Hematology & Clinical Pathology – Unsatisfactory – 1 CAPA filed
      Microbiology & Serology - Unsatisfactory – 1 CAPA filed
      Clinical Biochemistry - Unsatisfactory – 1 CAPA filed

10. The entire NCs raised in the internal audits are closed. (34 major and 31 minor)

11. The measures of Pre analytical/Analytical/ post analytical issues (Refer Point No.9)

12. **Continual Improvement.**
   a. From November 1st-2012 JKCN laboratory functions as collection center – monitored (application to be sent to NABL)
   c. Bar code generated for Out source tests.
   d. The record for transporting of specimens from pycrofts road is made online.
   e. Soft skill training programme conducted through training department by all laboratory staff members.
   f. MOU for Out source tests at Lister Metropolis laboratory extended for two years. (Dec 2012 to Dec 2014)
   g. Biomedical Dept & IT Dept have been included in Internal Audit Plan Dec’ 2012
   h. Histopathology protocol revised: Processing schedule for eyeballs, New staining technique for PAS Staining.
   i. Sharp Injury Procedure has been updated in QSM
   j. Verbal request procedure has been updated in QSM: restricted to blood grouping and glucose
k. New machineries:

   Histopathology: New Nikon Eclipse Ci Trinocular Microscope installed in September 2012

l. Version numbers of documents revised in 2012 (July to December)
   • Quarterly reporting of the Dy Technical Managers to the QM:SNSC/QREP/2012/ Isu-1.4
   • Lab Requisition Form : F/SNSC/ML/LRF/1.13
   • Eye Bank Requisition From : SNSC/MS/EBRF/1.2
   • Internal Customer Feed Back Form : SNSC/CFF/Microbiology/1.1
   • Internal Customer Feed Back Form : SNSC/CFF/OP/ Rev.1

m. Training programme: elaborate SOP is now given in the QSM/QSP

   Regular attendance by all technicians for soft skill training programme / evaluation / feedback
   and documentation of the same is now initiated. The newly created training department shall
   have all the details on training in the lab services apart from the respective laboratories.

n. Promotions & New posts created & New signing Authority (Refer Point No.10)

13. Vendor Evaluations

   • The approved vendor list prepared by the commercial after evaluation was
     Presented. No vendor is removed from the list. The list for 2013-14 will be circulated by the
     commercial

14. Other information:
   DESKTOP AUDIT: Desk top audit was conducted by NABL (June 2011 to May 2012) data was sent to
   NABL office. NABL recommended to continue the accreditation till August 2013.

   • Reminders:
     • Reviews: of contracts / records / SOP/ Calibration plan / status documentation of the obsolete
       record shredded
     • Inputs for vendor evaluation / material specification sheet to be monitored.
     • Interaction with clinical consultants to be documented and sent to QM for record.
     • Protocols to be followed on inclusion of new tests and included in the collection manual.
     • New books to be purchased to update the SOPs in all the laboratories.
     • Safety measures to be reviewed and training implemented/ evaluated.
     • Quality Plan for the year 2013 to be completed by the respective HODs.
• Documentation and Evaluation of training has to be effectively implemented through all the laboratories on co-ordination with the training department.
• The next external audit (Recertification audit) is due in May (or) June 2013.
• Scaling up of the sample flow and number of investigations to be planned and implemented

Thank You

Forwarded by:

Dr. N. Angyarkanni,
Quality Manager,
Medical Research Foundation
SNSC Laboratory
Chennai – 600 006.

Dr. S.B. Vasanthi
Management Representative
Medical Research Foundation
SNSC Clinical Laboratory
Chennai – 600 006.

Date: 18.03.2013.
Management Review meeting of SNSC performance based on External audit
Audit cycle-I - January to June 2013
Dated 11.09.2013

Attendance: By list (list enclosed). The representations were from the SN main lab for Hematology and Clinical Pathology, Routine Biochemistry, Sp. Biochemistry, Microbiology and Serology, Histopathology, Cytogenetics.

The stipulated agenda points of Management Review Meeting was reviewed in the laboratory service meeting.

1. Details Key points of the previous Management Review Meeting Minutes was reviewed

Audit Team Members and Audited labs/ Support services: Recertification audit form NABL was completed on 22nd and 23rd June, by the following team
- Quality Manual : Dr.N.Jayaram (Lead Assessor)
- Clinical Hematology & Pathology : Dr.Kalagara Madan (Technical Assessor)
- Clinical and Special Biochemistry: Dr.C.V.Anand (Technical Assessor)
- Microbiology and Serology : Dr.Kotari Hemalatharao (Technical Assessor)
- Histopathology and Cytopathology : Dr.Hema Kalagara (Technical Assessor)
- SNSC Collection Centre : Dr.N.Jayaram (Lead Assessor) and Dr.Kalagara Madan (Technical Assessor)

2. Status of Corrective and Preventive Actions taken (CAPA) : The QC reports of all the laboratories were verified every quarter. The following are the details of CAPA filed relevantly.

   a. EQAS / Daily QC-Clinical Hematology & Clinical Pathology lab : Unsatisfactory – 3 CAPA filed
   b. EQAS / Daily QC / ILQC - Clinical Biochemistry : Unsatisfactory – 8 CAPA filed
   c. EQAS Microbiology & Serology : Unsatisfactory – 2 CAPA filed
   d. ILQA Histopathology : Unsatisfactory – 2 CAPA filed
3. Report from Managerial and supervisory personnel of each of the lab on QC/Measures.
   - This has been reviewed for the two quarters in the last 6 months laboratory wise as per the format.
     (Proforma enclosed)

4. The Re-certification audit June’13 has been conducted by the external assessor and details of the outcome (non conformance -26) are given to the Heads of the lab respectively

5. Assessments of external bodies: updated in all the laboratories:
   a. Tamil Nadu Pollution control Board certificate for disposal of waste Renewal of Certificate has done on October 2012 (Validity till February 2016). Waste disposal is done by G.J Multiclane (approved) which will continue. Renewal of the agreement was done on May 2013 (Validity till April 2014)

6. Outcome of Quality Control: External/Internal/Daily of each lab: EQAS, ILQC.
   - The QC reports of all the laboratories (Refer Point No.2) completed as stipulated
   - Assessment of the referral labs was updated by all the departments – Completed.
     (Referral labs: Lister Metropolis, Hitech Diagnostic Centre, Sundaram Medical Foundation, Microbiological Laboratory-Coimbatore, Ehrlich laboratory, Sandor Proteomics Pvt ltd, SRMC – Porur, Anand Laboratory)
     (EQAS is done with: Biorad, CMC, AIIMS, SRL, IAMM, Euroimmun)

7. Volume and type of work undertaken
   - Revised Scope : Revised scope submitted to NABL office on June 2013. Results awaited.
     f. Clinical Haematology : 17 and Clinical Pathology : 19
     g. Clinical and Special Biochemistry : 20
     h. Clinical Microbiology and Serology : 26
     i. Histopathology : 6 and Cytopathology - 4
   
   Total: 92 Tests
• **Number of tests included / deleted as in the scope submitted to NABL:**
  
a. **Cl Microbiology and Serology:** ASO & Widal tests has been deleted and cANCA, pANCA tests has been included in the revised scope.
  
b. **Clinical and Special Biochemistry:** Inborn errors of metabolism test has been deleted and AST test has been included in the revised scope.
  
c. **Hematology and Clinical Pathology:** Bleeding Time and Clot Retraction tests has been deleted.

• **New signing Authority**
  
a. NABL recommended for Dr. J. Biswas (Histopathology) authorized signatory and for the rest of the signatories as applied for except the below
  
b. Request for Dr. K. Coral (Biochemistry lab) and Dr. Gayathri (Microbiology lab) for authorized signature, NABL not recommended due to lack of basic qualification in their respective discipline

• **New post created:** Nil.

• **Promotions/resignations:**
  
a. Four senior technicians from microbiology lab completed the probation period (Ms. Saranya, Ms. Priya, Mr. Gopinath & Ms. Parameshwari).
  
b. One senior executive from microbiology lab (Ms. Mohana Sundari), Two senior lab technicians (Ms. Jananee) – Hematology lab, (Mr. Gopinath) – Microbiology lab, One Secretary (Ms. Alamelu) – Hematology lab resigned the job.
  
c. One senior lab technician post (Hematology lab) has been converted to lab assistant, One secretary post has been surrendered.

**Refilling of the post:** Ms. Mohansundari, Senior executive post was not filled from Jan to Aug 13 and was filled up in September’13 (Ms. Vaidegi)- as Junior executive Mr. Gopinath, Senior Lab technician – resigned in June and the post was filled up in September’13 – (Mr. Hariram)
8. Feedback analysis:
   
a. **Internal customer feedback**: The observed measures (Jan – June 2013) were above the expected in all the laboratories. One of the Consultants had raised query / suggestion. This was addressed, action taken and settled.

b. **External customer feedback**: Feedbacks (after grouping them on similarity in issues) were analyzed (Jan – Jun 2013) proceeded with action and settled.

9. Quality Indicators for monitoring the laboratories contribution to patient care as measured
   
a. **Specimens receiving on time** - Satisfactory and met the objectives in all the labs.

b. **Turn around time** – Histopathology – Below the objective at 2 instances - 2 CAPA filed

c. **Machine downtime** – Clinical Biochemistry - Unsatisfactory – 2 CAPA filed

10. The entire NCs raised in the external audits are closed (15 major and 11 minor)

11. The measures of Pre analytical/Analytical/ post analytical issues (Refer Point No.9)

12. Continual Improvement.
   
a. Implemented all age wise normal ranges for PT & PTT.

b. Critical Alert values being sent online from 17th Jan 2013.

c. LH 750 Beckman Coulter (for Hematology lab) has been installed on 12.09.13.

d. Urine Routine Analysis along with microscopic examination has been shifted SNSC Collection Centre to SN Main lab form 24.06.13 onwards.

e. GTT Procedure was revised and followed ADA guideline. Instead of 5 specimens collection changed to only 3 specimens collection. Fasting, one hour and two hours collection from 20th Feb 2013.

f. Disposable Paper Cups used for GTT Patients from 22nd Feb 2013.

g. AST (SGOT) Test was shifted to Semi auto analyzer to Dade dimension fully automated method from 13th Feb 2013.
h. Total Protein, Albumin & AST Test was included in Liver Function Test package from 19th March 2013
i. Glucometer Validation Reports sent by online. Validation, Verification and Authorization was done by online from 4th March 2013
j. SNOWMED Coding of histopathology specimens in HMS done till lab ref no.530-13
k. Objective 85% is Raised to 90% Time interval between receiving the information and collection and transport of specimen from OT / Consultants room to Microbiology department – 40 minutes
l. Generation of Direct Smear Reports of clinical specimens by HMS within 6.00 hrs (Objective 85%) has been changed as 5.30 hrs (Objective 85%)
m. **Soft skill training programme for laboratory** Ms. Karpagapriya and Ms.Chandrika training department conducted 8 classes (Jan – June’13). Those who attended the training, details are recorded in the training record and also entered in the HMS.
n. MOU for ILQC tests at Lister Metropolis laboratory renewed for two years.
o. Daily NC Register has been created for all departments.
p. Quality Policy and Objectives has been updated
q. Version numbers of documents revised in 2013 (January to June)
   - Lab Requisition Form : F/SNSC/ML/LRF/1.14
   - Internal Audit Report : IAF/SNSC/09/Ver-1.2
   - Internal Audit Non-Conformance Report : IAF/SNSC/09/Ver-1.2
   - Internal Audit Check List : F/ IQA/AS Issue No: 1.1
   - Corrective and Preventive Action : SNSC/C&P/1.3
   - PMT / Calibration Plan : New Version 1.0
r. Promotions & New posts created & New Signing Authority (Refer Point No.7)
s. Website updated on SNSC lab.

13. **Vendor Evaluations**
   a. The approved vendor list prepared by the commercial for the period July to Dec 2013 has been circulated.

Issue Date : 18.09.13
Prepared & Issued by: Quality Manager
Approved by: Management Representative
14. Other information:
   
a. SNSC Collection Centre audited by external assessors (At HTP Block – JKCN Centre)

b. SNSC Collection centre shifted 1st floor to 5th floor (Same HTP block).

c. Problems in filling up of posts in Microbiology was discussed: Currently there are 3 vacancies in the 
   senior lab technicians grade, inspite of advertisements in the web site of SN.

- **Reminders:**

  - Reviews of contracts / records / SOP/ Calibration plan / status documentation of the obsolete record 
    shredded.
  - Inputs for vendor evaluation / material specification sheet to be monitored.
  - Interaction with clinical consultants to be documented and sent to QM for record.
  - Protocols to be followed on inclusion of new tests and included in the collection manual.
  - New books to be purchased to update the SOPs in all the laboratories.
  - Safety measures to be reviewed and training implemented/ evaluated.
  - Quality Plan for the year 2013 to be completed by the respective HODs.
  - Documentation and Evaluation of training has to be effectively implemented through all the 
    laboratories on co-ordination with the training department.
  - The next internal audit is due in December 2013.
  - Scaling up of the sample flow and number of investigations to be planned and implemented

**Thank You**

Dr. N. Angayarkanni,  
Quality Manager,  
Medical Research Foundation  
SNSC Laboratory  
Chennai – 600 006.

Forwards by:

Dr. S.B. Vasanthi  
Management Representative  
Medical Research Foundation  
SNSC Clinical Laboratory  
Chennai – 600 006.